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**STATUS OF CLAIMS:**

Claims 1-44 remain pending herein.

Support for the amendment of independent claims 1 and 29 can be found, for example, in claims 2, 3, 30 and 31. Support for a conductive polymer is found, for example, in paragraphs [0060] to [0062] of the specification. Support for electrodeposition in claims 3 and 31can be found, for example, in paragraph [0065]. The remaining claim amendments are self-explanatory, and are generally made to clarify the claims, to ensure consistency within the claims, or to address rejections under 35 U.S.C. §112, second paragraph. Hence, no new matter is introduced.

**REMARKS**

**Rejection of Claims 13-17, 23-24 and 41-42 under 35 U.S.C. §112, second paragraph**

Claims 13-17 are rejected under 35 U.S.C. §112, second paragraph, as indefinite. "The legal standard for indefiniteness is whether a claim reasonably apprises those of skill in the art of its scope." See, e.g., *In re Warmerdam* 33 F.3d 1354, 31 USPQ2d 1754 (Fed. Cir. 1994). That standard has been met by claims 13-17.

For instance, the Office Action asserts that claims 13-17: (a) are directed to the intended use of the device and (b) fail to provide any further structural limitations of the device. Applicant respectfully traverses this rejection. Regarding point "(a)" claims 13-17 go well beyond a mere statement of intended use. As a specific example, claim 13 requires that the cuff be adapted for placement around the urethra, which requirement clearly limits the ranges of sizes and shapes that the cuff can possess. Regarding point "(b)", it is respectfully submitted that the Applicant is free to use either functional or structural claim limitations in the claims, see, e.g., *In re Schreiber*, 128 F.3d 1473, 44 USPQ2d 1429 (Fed. Cir. 1997), and has elected to use the former in claims 13-15.

The Office Action further asserts that in claims 16-17, 23-24 and 41-42, the sensing system is not connected in any way to the rest of the device. Applicant respectfully traverses this rejection. As noted above, the legal standard for indefiniteness is whether a claim reasonably apprises those of skill in the art of its scope, and it is respectfully submitted that that standard is met by the claims. Moreover, the phrase "in communication with said control unit" has been

inserted into claims 16-17, 23-24 and 41, further rendering the rejection of these claims moot. Claim 42 recites no sensing system.

In view of the above, reconsideration and withdrawal of the rejections of claims 13-17, 23-24 and 41-42 under 35 U.S.C. 112, second paragraph, are respectfully requested.

**Rejection of Claims 1, 11-15, 20-22, 25-28 under 35 U.S.C. § 103(a)**

Claims 1, 11-15, 20-22, 25-28 are presently rejected under 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 6,162,238 ("Kaplan et al.") in view of U.S. Patent No. 6,514,237 B1 ("Maseda"). The Applicant respectfully traverses this rejection and its supporting remarks.

For example, independent claim 1 is presently directed to an artificial sphincter cuff that is adapted for placement around a body lumen and comprises, *inter alia*, a substrate layer, and an electroactive polymer active region that comprises a conductive polymer deposited on the substrate layer.

Kaplan et al., although stating at col. 2, line 66 that "[the] design of the actuator may vary widely," does not teach or suggest an actuator comprising an electroactive polymer active region that comprises a conductive polymer deposited on the substrate layer, as presently claimed in claim 1.

Maseda is cited for its disclosure of electroactive polymer actuators "for medical devices to induce many movements including expansion and contraction." However, in contrast to the *extra*luminal devices of Kaplan et al., the devices of Maseda are *intra*lumenal devices (see, e.g., title and abstract), for example, catheters, cannulae, guidewires and endoscopes (see col. 3, lines 58-64), all of which are far removed in principle of operation from artificial sphincters.

The Office Action refers to col. 3, lines 50-64, alleging that Maseda teaches that an electroactive polymer actuator can be used "in any type of device." However, like the remainder of Maseda, this section is clearly directed to intralumenal medical devices:

> The electroactive polymer strands may be embedded in *any type of flexible medical probe device*, including catheters, cannulae, guidewires and endoscopes. Although the electroactive polymer strands may be utilized in conjunction with any type of device, for ease of explanation, the exemplary embodiments described below will be with reference to a balloon catheter.

Maseda, col. 3, lines 58-64 (emphasis added).

Finally, the actuators described in Maseda are based on ion exchange polymers, rather than conductive polymers, as presently claimed in claim 1.

For at least the above reasons, it is respectfully submitted that claim 1 is patentable over Kaplan et al. in view of Maseda.

Claims 11-15, 20-22, 25-28 depend from claim 1 and are therefore patentable for over Kaplan et al. in view of Maseda for at least the same reasons as is claim 1.

Accordingly, Applicant respectfully requests reconsideration and withdrawal of the rejection of claims 1, 11-15, 20-22, 25-28 under 35 U.S.C. § 103(a) as obvious over Kaplan et al. in view of Maseda.

**Rejection of Claims 2-10 and 18-19 under 35 U.S.C. § 103(a)**

Claims 2-10 and 18-19 are rejected under 35 U.S.C. § 103(a) as obvious over Kaplan et al. and Maseda as applied above and further in view of U.S. Patent No. 6,249,076 ("Madden et al."). Applicant respectfully traverses these rejections and their supporting remarks.

For example, as noted above, claim 1 is presently patentable over Kaplan et al. in view of Maseda because these references neither teach nor suggest an artificial sphincter cuff which is adapted for placement around a body lumen and which comprises, *inter alia*, a substrate layer, and an electroactive polymer active region that comprises a conductive polymer deposited on the substrate layer.

Madden et al., while describing electroactive polymer actuators based on conductive polymers such as polypyrrole, says nothing about medical devices, much less artificial sphincters, and does not make up for deficiencies noted above in connection with Kaplan et al. and Maseda. For at least this reason, it is respectfully submitted that claim 1 is patentable over Kaplan et al. and Maseda and further in view of Madden et al.

Claims 2-10 and 18-19 depend from claim 1 and are therefore patentable for at least the same reasons as is claim 1.

Reconsideration and withdrawal of the rejections of claims 2-10 and 18-19 under 35 U.S.C. § 103(a) are therefore respectfully requested.

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**Rejection of Claims 29-40 and 43-44 under 35 U.S.C. § 103(a)**

Claims 29-40 and 43-44 are rejected under 35 U.S.C. § 103(a) as obvious over Kaplan et al., Maseda and Madden et al. as applied above and further in view of U.S. Patent No. 6,109,852 ("Shahinpoor et al."). Applicant respectfully traverses these rejections and their supporting remarks.

For example, independent claim 29 is presently directed to an artificial muscle patch that is adapted for placement adjacent a patient's heart and comprises, *inter alia*, a substrate layer, and an electroactive polymer active region that comprises a conductive polymer deposited on the substrate layer.

As noted above, Kaplan et al. is directed to implantable extralumenal systems for controlling flow through body lumens, and is therefore far removed in principle of operation from artificial muscle patches. Moreover, although Kaplan et al. states that "[the] design of the actuator may vary widely," Kaplan et al. does not teach or suggest an actuator comprising an electroactive polymer active region that comprises a conductive polymer deposited on the substrate layer, as presently claimed in claim 29.

Furthermore, the devices of Maseda are intralumenal medical devices and are also far removed in principle of operation from artificial muscle patches. In this regard, it is noted that the *intra*lumenal devices of Maseda are the virtual antitheses of the devices of Kaplan et al., which are *extra*luminal devices. In addition, the actuators described in Maseda are based on ion exchange polymers, rather than conductive polymers as presently claimed in claim 29.

Madden et al., while describing electroactive polymer actuators based on conductive polymers such as polypyrrole, says nothing about medical devices and thus does not make up for deficiencies noted above in connection with Kaplan et al. and Maseda.

Shahinpoor et al., although vaguely disclosing "a sphincter-type or a squeeze-type actuator used in medical applications for incontinence and cardiac-assist devices," does not teach or suggest an artificial muscle patch as claimed in claim 29. Nor does Shahinpoor et al. teach or suggest the use of electroactive polymer actuators comprising a conductive polymer as presently claimed in claim 29, but rather, like Maseda above, utilizes actuators based on ion exchange polymers.

For at least these reasons, it is respectfully submitted that claim 29 is patentable over Kaplan et al, Maseda, Madden et al. and Shahinpoor et al.

Claims 30-40 and 43-44 depend from claim 29 and are therefore patentable for at least the same reasons as is claim 29.

Reconsideration and withdrawal of the rejections of claims 29-40 and 43-44 under 35 U.S.C. § 103(a) are therefore respectfully requested.

**Statutory, "Same Invention" Double Patenting**

Claims 16-17, 23 and 41-42 are rejected under 35 USC 101 as claiming the same invention as that of claims 16-17, 23 and 41-42 of U.S. Patent No. 6,749,556.

This rejection is believed to be moot in view of the above amendments to claims 1 and 29. Reconsideration and withdrawal of this rejection are therefore respectfully requested.

**Obviousness-type Double Patenting**

Claims 1-15, 18-22, 24-40 and 43-44 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15, 18-22, 24-40 and 43-44 of U.S. Patent No. 6,749,556.

As noted in the Office Action, a timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground, provided the conflicting application or patent is shown to be commonly owned with the present application. A Terminal Disclaimer is enclosed herewith.

Accordingly, reconsideration and withdrawal of the outstanding rejection of the claims 1-15, 18-22, 24-40 and 43-44 under the judicially created doctrine of obviousness-type double patenting are respectfully requested.

**CONCLUSION**

Applicant submits that all pending claims are in condition for allowance, early notification of which is earnestly solicited. Should the Examiner be of the view that an interview would expedite the application at large, request is made that the Examiner telephone the Applicant's attorney at (703) 433-0510 in order to resolve any outstanding issues.

**FEES**

The Office is authorized to charge any fees required to deposit account number 50-1047.

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Respectfully submitted,

David B. Bonham
Registration No. 34,297

Attorney for Applicant
Mayer Fortkort & Williams, PC
251 North Avenue West, 2nd Floor
Westfield, NJ 07090
Tel.: 703-433-0510
Fax: 703-433-2362

**Certificate of Facsimile Transmission**

I hereby certify that this correspondence and any document referenced herein is being sent to the United States Patent and Trademark office via Facsimile to: 703-872-9302 on March 2, 2005.

David B. Bonham
(Printed Name of Person Sending Correspondence)

(Signature)